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EXAMINER

SHAY, DAVID M

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Concerning the rejection, applicants argue that the claims are patentable for at least the reasons made of record. In response, the examiner believes the claims to be obvious for the reasons of record, particularly in view of the Decision by the Board of Appeals rendered May 21, 2008.

Continuing, applicant argues that Frey merely teaches the adjusting a monofocal region to the patient's detected pupil size, and as such, only the outer periphery of the region is adjusted, rather than the outer periphery of both a first and a second region. Turning to Largent, applicant asserts the deficiencies of Frey are not cured thereby, apparently because Largent does not teach adjusting any aspect of the ablation shape with respect to pupil size. Hypothesizing as to what the combination would teach one of ordinary skill in the art, applicant concludes that as Frey only teaches adjusting the outer edge of the ablation zone, so one of ordinary skill in the art would only adjust the outer edge of the ablation zone in the combination. Regarding the newly added claims, applicant opines that these should be allowable, as they both contain the express limitation that the distribution of laser beam pulses for ablating both the first and second regions are determined in response to pupil size.

The examiner must respectfully disagree. Firstly with regard to the apparatus claims, it is instructive to compare the current independent apparatus claim to the apparatus claim that the Board of Appeals affirmed the rejection of:

Claims 10 as amended

Claim 17 as submitted

October 26, 2005

March 5, 2010

10 (Currently Amended) A system for treating a cornea of an eye of

17. (New) A system for treating a cornea of an eye of

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a patient to mitigate presbyopia with a multifocal ablation shape, the eye having a pupil and a cornea, the system comprising:
a laser for making a beam of an ablative light energy;
a processor in electrical communication with the laser; and
a tangible medium coupled to the processor and having stored instructions that, if executed by the processor, will cause the processor to perform operations comprising:
controlling a distribution of a series of laser beam pulses to ablate the multifocal shape on the eye, the the multifocal ablation shape producing a first region of the cornea providing a near vision correction and a second region of the cornea providing a far vision correction; and determining the distribution of laser beam pulses to ablate the first and second regions of the multifocal ablation shape where the distribution is determined in response to a signal related to a size of the pupil so as to balance the near vision correction and the far vision correction of the multifocal treatment for the patient.

a patient to mitigate presbyopia with a multifocal ablation shape, the eye having a pupil and a cornea, the system comprising:
a laser for making a beam of an ablative light energy;
a processor in electrical communication with the laser; and
a tangible medium coupled to the processor and having stored instructions that, if executed by the processor, will cause the processor to perform operations comprising:
controlling a distribution of a series of laser beam pulses to ablate the multifocal shape on the eye the the multifocal ablation shape producing a first region of the cornea providing a near vision correction and a second region of the cornea providing a far vision correction; and determining the distribution of laser beam pulses to ablate the first and second regions of the multifocal ablation shape where the distribution are determined in response to a signal related to a size of the pupil so as to balance the near vision correction and the far vision correction of the multifocal treatment for the patient.

As can readily be seen, the sole difference in the claims (the underlining in claim 10 indicates language that was added by the amendment of October 26, 2005) is the phrase “where the distribution is determined” (claim 10) and “where the distribution are determined” (claim 17) in the last indent of these claims (determining...), wherein the “are” appears to be intended to clarify that both regions are adjusted. Unfortunately, the originally filed disclosure merely gives a pair of examples as to how the adjustment may be implemented. There is no statement implicit

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or explicit in the originally filed disclosure that such an adjustment would exclude a scenario where the inner region was adjusted by a factor of 1, for example, such that all the change in area occurred in the outer region. However, even assuming that this were not the case, the Board of Appeals was unpersuaded by applicant's arguments to this effect, as set forth in the Decision on Appeal rendered May 21, 2008 (see pages 16 – 20 thereof):

We do not agree with Appellants that the Examiner failed to make out a prima facie case of obviousness based on Frey and Largent. Frey discloses a system that uses precisely directed laser energy to reshape a patient's cornea, thereby correcting vision deficiencies (FF 6). Thus, Frey's system meets claim 10's limitation requiring a cornea-ablating laser.

Frey discloses that, because it reshapes the cornea according to the diameter of a patient's dilated pupil, its system advantageously avoids the problems of hazy, blurred vision and halos that can occur in vision-correcting laser surgery (FF 7). To achieve this advantage, Frey's system includes an apparatus that determines the size of a patient's dilated pupil (FF 8).

Frey's pupil-measuring apparatus is connected to a cornea-shaping apparatus (see, e.g., Frey, Figure 1A (FF 8)). Frey's cornea-shaping apparatus is controlled by a "corneal sculpting program" (Frey, col. 3, l. 35 (FF 8)). The pupil-measuring apparatus inputs the data regarding the measured pupil size into the corneal sculpting program, which in turn directs the cornea-shaping apparatus to ablate the appropriately-sized optical zone (FF 8).

Because the cornea-shaping apparatus processes input regarding pupil size from the pupil-measuring apparatus, and because Frey's system has a pupil-size dependent corneal sculpting program that directs the cornea-shaping apparatus, we agree with the Examiner that Frey's system meets claim 10's limitation requiring the system to have a processor and tangible medium with instructions directing laser pulses to be distributed according to the patient's pupil size.

Frey's system does not have instructions controlling the laser's pulses such that the cornea is ablated to achieve a multifocal shape that corrects near and far vision. However, Largent discloses that it is desirable to use ablative laser energy to reshape a patient's cornea to have one region shaped to correct near vision, and another region shaped to correct far vision (FF 10-11).

Based on these disclosures, we agree with the Examiner that claim 10 would have been prima facie obvious to a person of ordinary skill in the art. A person of ordinary skill using Frey's system would have recognized from

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Largent that patients with deficient vision commonly required correction of both near and far vision (FF 10). One of ordinary skill would have further recognized from Largent that a solution to this common problem was to use ablative laser energy to reshape the patients' corneas to provide one region that corrects the near vision and a separate region that corrects the far vision (FF 10-1 1).

A person of ordinary skill would therefore have been prompted by Largent to include in Frey's system instructions directing the processor to determine the distribution of the laser's pulses so as to provide separate regions on the cornea to correct near and far vision, as recited in claim 10. Thus, because claim 10 in effect modifies Frey's system such that it applies an art-recognized solution to the known problem of correcting patients' near and far vision, we agree with the Examiner's prima facie case of obviousness.

Appellants argue that "the Examiner has not shown where the cited references teach or suggest 'determining the distribution of laser beam pulses to ablate the first and second regions of the multifocal ablation shape, where the distribution is determined in response to a signal related to size of the pupil. . .', as recited in claim 10" (App. Br. 10). Specifically, Appellants contend that Frey's disclosure is limited to "adjusting just one aspect of the ablation region in response to pupil size - i.e., the outer periphery or the overall extent of the region of the cornea subject to ablation," and that Frey therefore "fails to teach determining the distribution of laser beam pulses to ablate multiple regions of the multifocal ablation shape, particularly wherein the distribution is determined in response to a signal related to a size of the patient's pupil, as required by the current claims" (id.).

Appellants contend that Largent fails to remedy Frey's shortcomings because Largent discloses "a 'one size fits all' outer ablation shape and does not teach adjusting any aspect of an ablation shape based on pupil size" (id.). Appellants contend that, "[w]hile Largent's disregard of pupil size variations among different patients in determining the size for each of it[s] multiple regions may have been consistent with the thinking in the field at the time, the teachings of Largent are directly contrary to the invention as defined by claim 10" (id.). Appellants further contend that "the specific disregard of pupil size in the teachings of Largent would actually weigh against the proposed modification of Largent with the teachings of Frey to include adjusting ablation shape based on pupil size" (Reply Br. 7).

Appellants' arguments do not persuade us that the Examiner's conclusion of obviousness is erroneous. Appellants' arguments point out the shortcomings of each of the references when separately compared to the claims.

However, it is well settled that "[n]on-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references. . . . [The reference] must

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be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole." *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986).

Thus, as discussed above, when the references are properly viewed in combination with each other, a person of ordinary skill using Frey's system would have been prompted by Largent to include in Frey's system instructions for reshaping the cornea to achieve correction for both near and far vision. Moreover, because Frey discloses that matching the size of the reshaped portion of the cornea to the patient's dilated pupil size alleviates the blurred, hazy, and haloed vision problems that can result from corrective laser surgery (see FF 7, 9), we do not agree with Appellants that one of ordinary skill viewing the references in combination would have disregarded pupil size when applying Largent's near and far vision correction techniques to Frey's system.

Appellants argue that even if the two references' disclosures were combined, one would not arrive at the claimed invention because "Frey's approach changes only the overall size of the treatment without any change in shape. Thus, only one aspect of the ablation region (i.e., overall diameter of the ablated region) would be adjusted based on pupil size in the hypothetical combination of cited references" (App. Br. 11). Therefore, Appellants urge, the asserted combination of references would not teach "determining the distribution of laser beam pulses to ablate the first and second regions of the multifocal ablation shape, wherein the distribution is determined in response to a signal related to a size of the patient's pupil, as recited by claim 10" (*id.*; see also Reply Br. 8). Appellants further urge that the Examiner improperly relied on unsupported statements in finding that the references suggested these limitations (App. Br. 11 - 13).

We do not find Appellants' arguments persuasive. As pointed out above, the Supreme Court recently noted that the analysis under 35 U.S.C. 5103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).

In the instant case, we agree with the Examiner that one of ordinary skill in the art using Frey's system, being a person of ordinary creativity and common sense, *KSR*, 127 S. Ct. at 1742-43, would have reasonably inferred from Largent that it was desirable to reshape Frey's pupil-sized corneal optical zone into separate regions that corrected for both near and far vision, in patients requiring those vision corrections. Because failing to include both of Largent's reshaped corrective regions within Frey's pupil-sized optical zone would have defeated the purpose of Largent's multifocal correction, we agree with the Examiner that one of ordinary skill using Frey's system would have been prompted to modify the system with instructions directing the processor to determine the multifocal correction

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based on the optimal pupil-sized operative zone. Thus, we agree with the Examiner that claim 10's limitation, that the system includes instructions to determine multifocal-shaping laser pulse distribution "in response to a signal related to a size of the pupil," would have been obvious to one of ordinary skill in view of Frey and Largent.

Appellants argue that the Examiner failed to establish adequate motivation for combining the cited references (App. Br. 13). Specifically, Appellants urge that "if a presbyopia condition is correctable with the system of Largent as stated by the Examiner, one of ordinary skill would have no reason or motivation to then select a different system for presbyopia correction, and certainly would not be motivated to select the device of Frey," because Frey does not teach correcting presbyopia or ablating multiple focal regions of the eye (id. at 14). Moreover, Appellants argue, "Largent's focus on a 'one size fits all' ablation shape that specifically disregards pupil size, and which would not easily be adaptable for scaling of the outer periphery of the ablation shape, as taught by Frey, specifically weighs against the combination proposed by the Examiner" (id.).

We are not persuaded by these arguments. Appellants do not point to, nor do we see, any evidence that Frey's system would not have been adaptable to Largent's process. Rather, Frey discloses that its system provides a customized corneal sculpting based on a patient's pupil size, the reshaping including control of the depth of ablation required to provide a specific correction (see FF 9).

Moreover, because Frey explicitly discloses that its pupil-size-based eye reshaping system alleviates the blurred, hazy, and haloed vision problems that can result from corrective laser surgery (see FF 7, 9), we do not agree with Appellants that one of ordinary skill would have lacked motivation to use Frey's system to perform Largent's multifocal correction. Thus, given Frey's advantages of scaling the reshaped corneal zone based on pupil size, we do not agree that a person of ordinary skill practicing Largent's multifocal correction would have ignored Frey's disclosure.

It is clear that the arguments set forth in the instant response are equivalent to those argued in the Brief on Appeal. In responding, the Board particularly noted that "As pointed out above, the Supreme Court recently noted that the analysis under 35 U.S.C. 5 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR Int'l Co. v. TeleJZex Inc., 127 S. Ct. 1727, 1741 (2007). In the instant

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case, we agree with the Examiner that one of ordinary skill in the art using Frey's system, being a person of ordinary creativity and common sense, KSR, 127 S. Ct. at 1742-43, would have reasonably inferred from Largent that it was desirable to reshape Frey's pupil-sized corneal optical zone into separate regions that corrected for both near and far vision, in patients requiring those vision corrections.” Essentially, the reference to Largent discusses no particular ratios of the various near and far vision zones, thus the proper proportion of the area of the near vision zone to the far vision zone must have been part of the knowledge of one of ordinary skill in the art at the time of the invention of Largent. Otherwise, according to applicant's scenario of the actions of one of ordinary skill in the art, one of ordinary skill in the art would allow, in the event that the patient had a very small pupil diameter under fully dilated conditions, the outer annular correction to be completely eliminated, leaving only the monofocal correction of the inner area to treat the presbyopic eye. Clearly one of ordinary skill in the art, seeking to treat presbyopia would not do this. Further, as an evidentiary showing to this effect, the examiner respectfully invites applicants attention to the disclosures of U. S. Patent No. 5,812,238; U. S. Patent No. 5,507,979; and U. S. Patent No. 5,530, 491 all of which teach controlling the ratios of the sizes of the near vision and far vision zones in multifocal lenses (see column 2, lines 47-56; column 1, line 60 to column 2, line 5; and column 2, lines 12-18, respectively).

Claims 1-9 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frey in combination with Largent. Frey teaches a laser surgical system including a laser and a processor and scaling the ablation to the pupil size (see column 1, lines 5-10 and column 2, lines 46-55). Largent teaches designing a corneal ablation to mitigate presbyopia. It would have been obvious to the artisan of ordinary skill to employ the device of Frey on a subject with presbyopia, since

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this condition is correctable with laser sculpture as taught by Largent, or to employ the pupil scaling device of Frey in the presbyopia treating system of Largent, since this would reduce the halo effect and improve night vision, as taught by Frey, thus producing a method such as claimed.

Claims 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frey in combination with Largent. Frey teaches a laser surgical system including a laser and a processor and scaling the ablation to the pupil size (see column 1, lines 5-10 and column 2, lines 46-55). Largent teaches designing a corneal ablation to mitigate presbyopia. It would have been obvious to the artisan of ordinary skill to employ the device of Frey on a subject with presbyopia, since this condition is correctable with laser sculpture as taught by Largent, or to employ the pupil scaling device of Frey in the presbyopia treating system of Largent, since this would reduce the halo effect and improve night vision, as taught by Frey, thus producing a device such as claimed.

Applicant's arguments filed March 5, 2010 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Monday through Thursday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson, can be reached on Monday through Friday from 7:00 a.m. to 3:30 p.m. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/david shay/

Primary Examiner, Art Unit 3769